

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING	)	
PHARMACY, INC. PRODUCT LIABILITY	)	MDL No. 02419
LITIGATION	)	Docket No. 1:13-md-2419-RWZ
_____	)	
	)	
This document relates to:	)	
	)	
All of the cases against the Box Hill Defendants <sup>1</sup>	)	

**PLAINTIFFS’ OPPOSITION TO BOX HILL DEFENDANTS’ MOTION FOR LEAVE  
TO FILE MOTIONS FOR SUMMARY JUDGMENT**

Pursuant to the Court’s February 3, 2017 Order (Dkt. 3301), Plaintiffs submit their opposition to Box Hill Defendants’ Motion for Leave to File Motions for Summary Judgment (Dkt. 3439) (“Motion for Leave”).<sup>2</sup> The motion should be denied for the following reasons:

1. In ruling on Defendants’ motion to dismiss all claims (Dkt. 2225) and approving a stipulation by the parties that certain claims are dismissed and that other claims would survive that motion (Dkt. 1761 and Dkt. 1780), this Court has permitted the following claims to proceed against the Box Hill Defendants: medical malpractice - negligence, informed consent, violation of Mass. Gen. Laws ch. 93A, wrongful death, loss of consortium, and punitive damages. To succeed on summary judgment a moving party must carry a heavy burden. *De Abadia v. Izquierdo Mora*, 792 F.2d 1187, 1204 n.19 (1st Cir. 1986); *see also Hartel v. United States*, No. 02-10101-NG, 2004 U.S. Dist. LEXIS 28242, at \*13 (D. Mass. Oct. 12, 2004) (Gertner, J.) (observing a presumption

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<sup>1</sup> Armetta v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14022-RWZ; Bowman v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14028-RWZ; Davis v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14033-RWZ; Dreisch v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14029-RWZ; Farthing v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14036-RWZ; Kashi v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14026-RWZ; Torbeck v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14023-RWZ; Handy v. Box Hill Surgery Center, LLC, et al., No. 1:14-cv-14019-RWZ.

<sup>2</sup> Plaintiffs have not requested leave to file summary judgment motions as Defendants’ motion alludes to. *See* Dkt. 3439 at 5.

against summary judgment in negligence cases).<sup>3</sup> In this case Defendants cannot prove their entitlement to summary judgment on any of the issues listed in their Motion for Leave. *See* Dkt. 3439 at 1-2. Entertaining the suggested motions would be a waste of the Court's and counsels' time and resources.

### **Compliance with the Appropriate Standard of Care**

2. Plaintiffs' two general medical liability experts, Lloyd Saberski, MD and Shmuel Shoham, MD, collectively detail in their reports (true copies annexed, Exhibit A and Exhibit B, respectively) and deposition testimony Defendants' violations of applicable standards of care when they (1) purchased and administered NECC compounded methylprednisolone acetate ("MPA") despite the availability of FDA approved benzyl alcohol-free deposit steroids; (2) failed to comply with applicable Massachusetts or Maryland statutes, regulations, or guidelines governing the prescription and dispensing of compounded prescription medication for patients; (3) failed to inform patients that NECC's MPA was a compounded and not a FDA approved manufactured steroid; and (4) negligently used benzyl alcohol preservative-free multi-dose vials of steroidal preparations rather than single-dose vials.

3. Defendants' unsupported suggestion that Plaintiffs' experts' opinions are unreliable is not only wrong, but is irrelevant at this juncture. *See Den Norske Bank AS v. First Nat'l Bank of Boston*, 75 F.3d 49, 58 (1st Cir. 1996) ("At summary judgment . . . courts normally

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<sup>3</sup> "The role of summary judgment is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Chapman v. Bernard's, Inc.*, 167 F. Supp. 2d 406, 411 (D. Mass. 2001) (internal quotations and citations omitted). Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "A genuine issue is one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant would permit a rational fact finder to resolve the issue in favor of either party." *Yerardi v. Pac. Indem. Co.*, 436 F. Supp. 2d 223, 237 (D. Mass. 2006) (internal quotations and citations omitted).

assume that the trier of fact would credit the expert testimony proffered by the nonmovant.”). There being no *Daubert* ruling precluding them, Box Hill is putting the cart before the horse.

4. There is thus an incontrovertible dispute regarding the Defendants’ compliance with the recognized standard of acceptable professional practice that utterly precludes the entry of summary judgment in their favor.

### **Due Diligence, Foreseeability, and Superseding, Intervening Cause**

5. “Proximate causation and intervening cause are usually issues for the jury to resolve.” *Wortley v. Camplin*, 333 F.3d 284, 295 (1st Cir. 2003); *see also Staelens v. Dobert*, 318 F.3d 77, 79 (1st Cir. 2003) (observing that the question of proximate cause, whether a risk of harm was reasonably foreseeable, is ordinarily for the jury).

6. Plaintiffs’ medical experts opine that Defendants failed to evaluate the source of MPA, and thus failed to learn of available data and information demonstrating that compounders engaged in mass production of drugs were at significantly greater risk for contamination or other defects than FDA compliant manufacturers, and thus failed to exercise reasonable and prudent care to ensure that (1) NECC’s steroid preparations used for injections were sterile, free of contaminants, and compounded in accordance with all applicable industry standards; and (2) NECC reliably and consistently utilized proper quality control, safety, and sterility measures so as to minimize or eliminate the possibility that the drugs were not sterile or contaminated.

7. Had Defendants acted prudently and with due diligence, they would not have, as they did, purchased MPA from NECC precisely because of the risks to their patients posed by the significantly higher risk of contamination in mass compounded products.

8. Plaintiffs through their experts, as well as other evidence about previous infection outbreaks involving sterile compounded drugs, will therefore present evidence that the

contamination event was reasonably foreseeable to, and the harm preventable by, Defendants. Foreseeability and superseding, intervening causes are therefore issues of disputed material facts appropriate for disposition at trial.

### **Punitive Damages**

9. As the Court observed in its September 8, 2015 Memorandum Opinion (Dkt. 2225), “[i]n Maryland, punitive damages may be awarded upon a showing of actual malice, characterized by evil motive, intent to injure, ill will, *or fraud*.” Dkt. 2225 at 7 (internal quotations and citation omitted) (emphasis added).

10. Plaintiffs’ expert, Dr. Saberski, observed that prior to the infection outbreak in 2012 Defendant Dr. Bhambhani never discussed with Plaintiffs the fact that she was administering a mail ordered steroid medication made by a compounding pharmacy nor any of the risks of using a compounded and not FDA approved manufactured injectable steroid product.

11. Further, in violation of FDA, Massachusetts, and Maryland laws or regulations, Dr. Bhambhani provided NECC lists of names of prior patients who had already received MPA to illegally order MPA in bulk, and then administered portions of the bulk purchased MPA dispensed and designated for a specific patient to a different patient, all without informing the patient receiving the MPA that she originally purchased the MPA for someone else. Such is outrageous conduct.

12. Thus, contrary to Defendants’ claim, there is ample proof evidencing that punitive damages is an appropriate remedy for Defendants’ conduct.

### **Plaintiffs’ Massachusetts Consumer Protection Claim**

13. Mass. Gen. Laws ch. 93A “is clear, if extraordinarily broad,” in protecting consumers from abuse and harm, and here there can be no question that Defendants’ bulk ordering

of MPA from NECC under false names in violation of Massachusetts' pharmacy laws adopted to protect consumers' health and safety "had some effect, directly or indirectly, on persons within Massachusetts" and is actionable. *See* Dkt. 2225 at 6-7 allowing claim. As such, Plaintiffs can present sufficient evidence to raise a genuine dispute of material fact as to whether recovery under Mass. Gen. Laws ch. 93A is appropriate.

### **Plaintiffs' Recoverable Medical Expenses under Maryland Law**

14. Defendants improperly suggest that summary judgment is appropriate to reduce damages Plaintiffs may be awarded to compensate them for medical expenses incurred as a result of the injuries sustained in these cases. Quite simply, under both Maryland and Massachusetts law, Defendants are not "entitled" to credit for expenses paid for the benefit of Plaintiffs by insurers or paid to them by other third-party sources. In both States, there are statutory post-verdict procedures through which a defendant in a medical malpractice case may ask the court to reduce a verdict for past medical expenses. *See* Dkt. 2452 at 4-6 (Memorandum in Support of Plaintiffs' Motion to Strike Certain Affirmative Defenses, Cross-Claims, and Third Party Claims).

For the foregoing reasons, Plaintiffs respectfully request the Court deny Box Hill Defendants' Motion for Leave to File Motions for Summary Judgment.

Respectfully submitted,

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